

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : H.-H. Weil and O. Daab ) Art Unit: To be assigned  
U.S. Appln. No. : To be assigned /0633987 ) Examiner: To be assigned  
Confirmation No. : To be assigned  
U.S. Filing Date : August 12, 2003  
Title of Invention : SUSPENSION AEROSOL FORMULATIONS OF  
PHARMACEUTICAL PRODUCTS  
Attny. Docket No. : 3/334-6-C5

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

August 27, 2003

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,



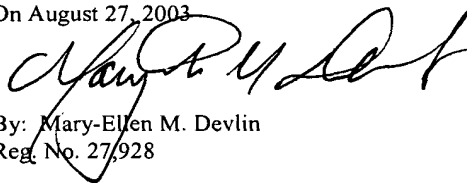
Mary-Ellen M. Devlin  
Attorney for Applicant(s)  
Reg. No. 27,928

Patent Department  
Boehringer Ingelheim Corp.  
900 Ridgebury Road  
P.O. Box 368  
Ridgefield, CT. 06877  
Tel.: (203) 798-4868

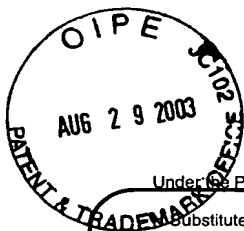
I hereby certify that this correspondence is being  
Deposited with the U.S. Postal Service as First  
Class Mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

On August 27, 2003



By: Mary-Ellen M. Devlin  
Reg. No. 27,928



PTO/SB/08a (05-03)

Approved for use through 05/31/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

|                        |                      |
|------------------------|----------------------|
| Application Number     | To be assigned       |
| Filing Date            | August 12, 2003      |
| First Named Inventor   | H-H WEIL and O. DAAB |
| Art Unit               | To be assigned       |
| Examiner Name          | To be assigned       |
| Attorney Docket Number | 3/334-6-C5           |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|---|
|                    |                       | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
|                    |                       | US- 4,044,126                            | 08/23/1977                     | P. B. Cook et al.                                  |   |
|                    |                       | US- 5,118,494                            | 06/02/1992                     | R. K. Schultz et al.                               |   |
|                    |                       | US- 5,653,962                            | 08/05/1997                     | R. A. Akehurst et al.                              |   |
|                    |                       | US- 5,695,743                            | 12/09/1997                     | T. S. Purewal et al.                               |   |
|                    |                       | US- 4,814,161                            | 03/21/1989                     | P.A. Jinks et al.                                  |   |
|                    |                       | US- 4,352,789                            | 10/05/1982                     | C. G. Thiel  |   |
|                    |                       | US- 5,674,471                            | 10/07/1997                     | Akehurst et al.                                    |   |
|                    |                       | US- 4,810,488                            | 03/07/1989                     | P. A. Jinks  |   |
|                    |                       | US- 4,174,295 A                          | 11/13/1979                     | Bargigia et al.                                    |   |
|                    |                       | US- 5,182,097 A                          | 01/26/1993                     | Byron and Dalby                                    |   |
|                    |                       | US- 5,605,674 A                          | 02/25/1997                     | Purewal and Greenleaf                              |   |
|                    |                       | US- 6,153,173 A                          | 11/28/2000                     | Sapsford and Savage                                |   |
|                    |                       | US- 5,891,420                            | 04/06/1999                     | A. J. Cutie  |   |
|                    |                       | US- 6,149,892                            | 11/21/2000                     | I.L. Britto  |   |
|                    |                       | US-                                      |                                |  |   |
|                    |                       | US-                                      |                                |  |   |
|                    |                       | US-                                      |                                |  |   |
|                    |                       | US-                                      |                                |  |   |

**FOREIGN PATENT DOCUMENTS**

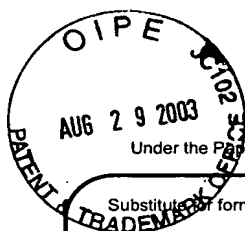
| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|---|--------------------------------|--|---|----------------|
|                    |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                    |                       | WO 86/04233   | 07/31/1986                     | Riker Labs., Inc.                                  |   |                |
|                    |                       | EP 0 247 608  | 12/02/1987                     | Richardson-Vicks, Inc.                             |   |                |
|                    |                       | GB 902,590  | 08/01/1962                     | Allied Chemical, Corp.                             |   |                |
|                    |                       | CA 2,075,058  | 08/04/1991                     | Boehringer Ingelheim<br>International GmbH         |   |                |
|                    |                       | JP 55 131 096   | 12/1980                        |  |   |                |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



|   |   |                          |                      |                        |            |
|---|---|--------------------------|----------------------|------------------------|------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   | <b>Complete if Known</b> |                      |                        |            |
|   |   | Application Number       | To be assigned       |                        |            |
|   |   | Filing Date              | August 12, 2003      |                        |            |
|   |   | First Named Inventor     | H-H WEIL and O. DAAB |                        |            |
|   |   | Art Unit                 | To be assigned       |                        |            |
|   |   | Examiner Name            | To be assigned       |                        |            |
| Sheet   | 2 | of                       | 3                    | Attorney Docket Number | 3/334-6-C5 |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.             | T <sup>2</sup> |
|                                 |                       | DU PONT: Fluorocarbon/Ozone: Alternatives to Fully Halogenated Chlorofluorocarbons: The Du Pont Development Program; March 1987   |                |
|                                 |                       | Research Disclosure, May 1989, Kenneth Mason Publications Ltd., ISSN 0374-4353  |                |
|                                 |                       | T. S. Johnson and H. Deger of Hoechst Celanese Corp., "Specialty fluoroaliphatic chemicals," a paper presented at Chemspec USA 1989, pages 61-63, a symposium highlighting innovation, <u>manufacture and applications of specialty chemicals, held 10-11 October 1989.</u> |                |
|                                 |                       | F.X. Fischer et al. "CFC Propellant Substitution: International Perspectives," Pharm. Technol. Inc., 1989, 1(2), 16-18.   |                |
|                                 |                       | L. Lachman et al., "The Theory of Practice of Industrial Pharmacy," Philadelphia, Ch. 20, p 590 and 603-604, 1986.  |                |
|                                 |                       | Hoeschst Press Realease #7252, "Hoechst: Development of Alternatives to Fully Halogenated CFC's Takes Priority" October 25, 1989.   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |

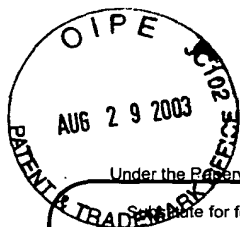
|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08a (05-03)

Approved for use through 05/31/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 3

**Compleat if Known**

|                        |                        |
|------------------------|------------------------|
| Application Number     | To be assigned         |
| Filing Date            | August 12, 2003        |
| First Named Inventor   | H.-H. WEIL and O. Daab |
| Art Unit               | To be assigned         |
| Examiner Name          | To be assigned         |
| Attorney Docket Number | 3/334-6-C5             |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|--------------------|-----------------------|---|--------------------------------|--|---|
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |
|                    |                       | US-   |                                |  |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document<br>Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|--|--------------------------------|--|---|----------------|
|                    |                       | EP 0 384 371 A1  | 08/29/1990                     | Hoechst Aktiengesellschaft                         |   |                |
|                    |                       | EP 0 384 371 A1 (translation)  | 08/29/1990                     | Hoechst Aktiengesellschaft                         |   |                |
|                    |                       | EP 0 315 783   | 05/17/1989                     | Bayer AG   |   |                |
|                    |                       | WO 91/11173  | 08/08/1991                     | Fisons PLC   |   |                |
|                    |                       | DE 39 03 336 A1  | 08/09/1990                     | Bayer AG   |   |                |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.